

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/550,165	SAVAGE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ganapathy Krishnan	1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to RCE filed 4/27/2009.
2. ☒ The allowed claim(s) is/are 1,2,18 and 24-30.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date <u>4/27/09</u></li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date <u>7/23/2009</u> .</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
|---|--|

/Shaojia Anna Jiang/  
Supervisory Patent Examiner, Art Unit 1623

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Eric DeMaster on July 23, 2009.

In the Amendments to the Claims of 4/27/2009:

The terms "Listing of Claims" have been replaced by the terms "We Claim".

In Claim 18, line 2, the terms "claim 1" have been inserted after the terms "Formula (I)".

In Claim 24, line 1, the terms "claim 1" have been inserted after the terms "Formula (I)".

In Claim 25, line 1, the terms "in claim 1" have been inserted after the terms "Formula (I)".

### **REASONS FOR ALLOWANCE/ EXAMINER'S AMENDMENT**

The following is an examiner's statement of reasons for allowance:

1. The closest prior art of record, Kawano et al (Science, 1997, 278(28), 1626-29) teaches the glycosylceramide,  $\alpha$ GalCer (page 1627, Fig. 1, second formula on the right) and the activation of  $V_{\alpha}14$  NKT cells by this compound. The difference between Kawano's compound and the instant compound of formula (I) is that Kawano's compound has a hydroxyl group at the C-6 position of the sugar ring. The sugar ring in the instant compound of formula (I) has an

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aminoacyl group at the C-6 position. There is no teaching or suggestion in Kawano regarding the replacement of the C-6 hydroxyl with an aminoacyl group.

2. Tsuji et al's (US 7,273,852) compound of formula (I) (col. 6) has a sugar ring having an amino group at the C-6 position but one of the substitutions on the nitrogen of the amino group is either hydrogen or a monosaccharide and not an aminoacyl as instantly claimed. Moreover, in Tsuji's compound the anomeric carbon of the sugar ring is linked to the lipid chain via a  $-CH_2-$  whereas in the instant compound the sugar ring is linked via oxygen. There is no teaching or suggestion in Tsuji et al for modifying his compound in both the sugar ring and the lipid part with the substitutions as instantly claimed. Both Kawano and Tsuji do not render obvious the use of instant compound of formula (I) in combination with a CD1d protein in a method of stimulating NKT cells. There is also no reasonable expectation of success that substitution of Kawano's compound with the instant compound would activate (or stimulate) NKT cells since even minor structural modifications can cause drastic changes in activity.

3. Regarding the method of making the compound of instant formula (I), even though Sinay and Defrees teach reduction of an azide to amino group and sulfonylation of an amino group respectively, their reactions are performed on carbohydrate oligomers. In the instant process the reduction of the azide group to an amino and subsequent acylation of the amino nitrogen are performed on a substrate that is structurally different. The instant process is not taught or rendered obvious by Sinay and Defrees.

Any comments considered necessary by the applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Any inquiry concerning this communication should be directed to Shaojia A. Jiang,  
Supervisory Patent Examiner in Art Unit 1623 at 571-272-0627.

/Shaojia Anna Jiang/

Supervisory Patent Examiner, Art Unit 1623